K030297

APR 2 8 2003

ENRAF NONIUS

Partner for Life

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Trade Register No.: 272.30.375

510(k) Summary Flexible Rubber Electrodes 1460265/272/274 and 3444128/129/130

510(k) Number :

Date of Preparation : January 21, 2003

Contact Person : Mr. Rick Coelet
Project Manager

Device Name : Flexible Rubber Electrodes
Common Name : Reusable electrodes for electrical stimulation.
Classification Name : Electrode, Cutaneous

Predicate Device : K880699
Endomed CV405 and Accessories

Device Description

The Flexible Rubber Electrodes are a family of electrodes that are supplied as accessories to Enraf-Nonius B.V. nerve and muscle stimulation equipment. Depending on electrode size and connection terminals, the following parts apply:

1460265	6 x 8 cm electrode with 4 mm female connection terminal
1460272	4 x 6 cm electrode with 4 mm female connection terminal
1460274	8 x 12 cm electrode with 4 mm female connection terminal
3444128	4 x 6 cm electrode with 2 mm female connection terminal
3444129	6 x 8 cm electrode with 2 mm female connection terminal
3444130	8 x 12 cm electrode with 2 mm female connection terminal

The electrodes consist of carbon filled silicon rubber. For proper electrical contact with the patient the electrodes should be used in combination with moistened sponge pads. The electrode/sponge assembly is wrapped to the patient using fixation straps. Instructions for use are available in the Operating Instructions of the Enraf-Nonius B.V. nerve and muscle stimulators that the electrodes are to be used with. The following accessories apply:

1460266	Sponges Pads 6 x 8 cm, set of 4 pc
1460273	Sponges Pads 4 x 6 cm, set 4 pc
1460275	Sponges Pads 8 x 12 cm, set 4 pc
3444020	Fixation strap 100 x 3 cm
3444021	Fixation strap 250 x 3 cm

510(k) Summary Flexible Rubber Electrodes 1460265/272/274 and 3444128/129/130

Indications for Use Statement

510(k) Number :

Applicant : Enraf-Nonius B.V.

Device Name : Flexible Rubber Electrodes

Indications for Use:

Electrical Stimulation

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

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Substantial Equivalence Summary

Electrodes 1460265, 1460272 combined with sponge pads 1460266 and 1460273, were already used as accessories to the Enraf-Nonius B.V. Endomed CV405 powered muscle stimulator, a device no longer in production. The electrodes were continued to be used with newer Enraf-Nonius B.V. stimulator designs marketed outside the USA. During this time the electrodes have undergone the following changes:

- Electrode size 8 x 12 cm was added to the family
- Electrodes were made available with 2 mm female terminations
- A new material formulation was used

Comparison of Technological Characteristics:

Device	New	Predicate
Maximum Current Density: Electrode size : 4 x 6 Stimulation current : 100 mA r.m.s. (IEC 60601-2-10 limit at frequencies above 1500 Hz)	4.2 mA/cm²	4.2 mA/cm²
Maximum Power Density: Electrode size : 4 x 6 Current type : Premodulated carrier freq : 2 kHz beat freq : 0 Hz amplitude : 100 mA Current type : Diadynamic DP amplitude : 70 mA (measured with sponge pads moistened with tap water)	< 25 mW/cm² < 50 mW/cm²	< 25 mW/cm² < 50 mW/cm²
Standards: IEC 60601-1 (1988+A1+A2) IEC 60601-2-10 (1987) MDD 93/42/EEC 21 CFR 898	Yes Yes Yes Yes	Yes Yes Yes Yes
Biocompatibilty according to ISO 10993: Cytotoxicity Skin Irritation Dermal Sensitization	Yes Yes Yes	Yes Yes Yes

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 8 2003

Mr. Rick Coelet
Enraf-Nonius, B.V.
Rontgenweg 1, 2624 BD Delft
P.O. Box 810, 2600 AV Delft
The Netherlands

Re: K030297
Trade/Device Name: Flexible Rubber Electrodes
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: Class II
Product Code: GXY
Dated: January 24, 2003
Received: January 28, 2003

Dear Mr. Coelet:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

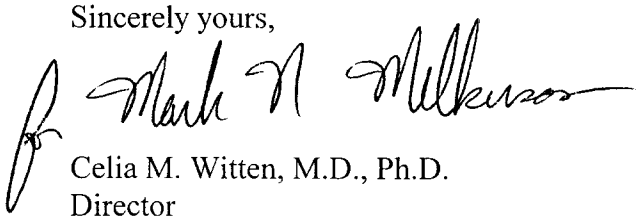
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if

applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-__. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, M.D., Ph.D.
Director
Division of General, Restorative, and
Neurological Devices
Office of Device Evaluation
Center for Devices and

Enclosure

510(k) Summary Flexible Rubber Electrodes 1460265/272/274 and 3444128/129/130

Indications for Use Statement

510(k) Number : K030297

Applicant : Enraf-Nonius B.V.

Device Name : Flexible Rubber Electrodes

Indications for Use:

Electrical Stimulation

for Mark N Milkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K030297

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)

(Optional Format 1-2-96)